

Original Article

Effectiveness of new pelvic floor exercises on urinary incontinence in older women with cognitive impairment: A pilot study at long-term care facilities

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Key words

cognitive impairment, older adults, pelvic floor muscle exercise, residual urine volume, stress urinary incontinence

Abstract

Background Stress urinary incontinence (SUI) is one of the most severe morbidities in older women, with a large impact on daily life. SUI in long-term care facilities is uneasy to manage because it is likely to be accompanied by mobility and/or cognitive impairment and there have been hardly developed effective physical therapy in this population. The aim of this pilot study is to evaluate a newly designed pelvic floor muscle (PFM) exercise in reducing urinary problems among cognitively impaired older women who have symptoms of SUI.

Method A non-randomized controlled trial was conducted on sixteen older women aged seventy or older with SUI at three long-term care facilities in Japan. The intervention group performed the new PFM exercise once a day for 8 weeks in addition to ordinary care at the facilities. Otherwise, only the ordinary care which included prompted voiding and scheduled toileting was performed for the control group. A diurnal bladder diary for three days and the residual urine volume (RUV) were documented before and after the intervention period.

Results Six participants for the intervention group and five for the control group completed the study protocol. After eight weeks of intervention, there was a significantly greater reduction in RUV in the intervention group ($p=0.009$). There were no significant changes in frequency or severity of urinary leakage among both groups.

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Conclusion The new PFM exercise was effective for cognitively impaired older women to attenuate RUV. The result indicates the residual urine is a concomitant condition of SUI in older women and the physical therapy may improve their urinary problems.

Key words: cognitive impairment, older adults, pelvic floor muscle exercise, residual urine volume, stress urinary incontinence

Introduction

The urinary problems in women are characterized by an increased risk of stress urinary incontinence (SUI) with aging, a complaint of involuntary urine leakage upon an increased intra-abdominal pressure due to sneezing or coughing¹. The prevalence of SUI is 50% among women of all ages and it is the most common cause of urinary incontinence in women². In long-term care facilities, the prevalence rate of urinary incontinence reaches 40 to 70%³, resulting in loss of independence in daily life. Therefore, improving SUI has been a significant challenge for healthy and independent lives of older women.

Urethral sphincter dysfunction and urethral support problems are the major aspects of this morbidity. Urethral sphincter dysfunction is caused by nerve injury due to intrapelvic surgery or delivery. Urethral support problems are related to declining pelvic floor support, illustrated by histological changes such as decreased collagen in connective tissue or altered muscle fibers. Smith *et al.* reported that denervation of the pubococcygeous muscle was a normal accompaniment of aging and parity, and it was significantly obvious in genitourinary prolapse and SUI⁴. There were less amounts of neuropeptide in striated muscle and connective tissues of the pelvic floor among these cases^{5,6}. Levator ani is a voluntary muscle that consists of mainly type I (large diameter slow-twitch) and type II (fast-twitch) fibers and supports the pelvic floor with endopelvic fascia^{7,8}. It also supports the vesical neck and urethra with constant tone as well as responded contraction against abdominal pressure and keep continence, compressing the urethra simultaneously⁹. Among women, the diameters of type I and type II fibers in levator ani become small due to aging and menopause. SUI and prolapse cases have significantly smaller

diameter muscle fibers¹⁰, and the muscles are significantly thinner than those of asymptomatic cases^{11,12}. SUI cases also show ragged-red fibers with Gomori's trichrome stain, which indicate necrosis and degeneration of type I fibers¹⁰. Thus, such denervation-related muscle alteration is the major characteristics in SUI, which indicates vulnerable pelvic floor to cause urine to leak.

Minimal invasive surgeries for restoring vesical neck support such as the tension free vaginal tape procedure or the transobturator vaginal tape procedure have been introduced in the last decade for the treatment of SUI, but those treatments are accompanied by various post-operative complications, such as voiding difficulties, increased post-void residual urine or newly onset urge symptoms, resulting in re-operation¹³⁻¹⁶. Pharmacotherapy is used to increase bladder outlet resistance, but not recommended for SUI¹⁷. Behavioral therapy is a non-invasive and less harmful measure, and it should be implemented prior to a surgical treatment. For example, prompted voiding and bladder training are recommended by guidelines¹⁸, that are effective for the urinary incontinence in institutionalized older adults^{19,20}. Since advocated by Kegel and Bø, it has been reported in plenty of studies that the pelvic floor muscle exercise is effective for SUI²¹⁻²³. The pelvic floor exercise is now a common behavioral therapy for SUI, which is usually implemented with biofeedback under expert guidance, using devices such as a manometer or an electromyography in a transvaginal or a trans-rectal way or digital vaginal palpation to contract and relax the pelvic floor muscles properly. The pelvic floor exercise is regarded as an effective method to improve SUI in the older women^{24,25}, however, few studies have implemented the exercise for the older people in long-term care facilities. Part of the reason is

that cognitive decline as well as frailty or inactiveness are general conditions among them¹⁹⁾. The development of urinary incontinence is highly associated with physical and cognitive impairments among the institutionalized older adults²⁶⁾. Both those conditions are likely to be the factors of less compliance along with the pelvic floor muscle exercise because such impairments make it difficult to recognize precise muscles to contract, obtain the exercise techniques and train the muscles effectively by themselves²⁷⁾²⁸⁾. Therefore, physical therapy for SUI is hardly accommodated to the older people with cognitive decline²⁹⁾, and a feasible method is required for successful exercise among this population. The physical intervention should be simple and easy as well as appropriate to train the aged muscles continuously and effectively. This pilot study aimed to evaluate a newly designed pelvic floor muscle exercise in reducing urinary problems among cognitively impaired older women with symptoms of SUI at long-term care facilities. This report is belonging to the first author's master's thesis.

Methods

1. Design

This is a pilot study and a non-randomized controlled trial with two groups. One group was the intervention group with a new pelvic floor muscle exercise and the ordinary care in the collaborating facilities, and the other was a control group which underwent the ordinary care only. Participants were recruited by nursing units; three participating units belonging to different long-term care facilities in the Chiba and the Saitama Prefecture, two units were allocated into the intervention group and one unit into the control group. All three groups provided patients with a similar continence care using scheduled toileting and prompted voiding. Because the purpose of the exercise was explained to each participant in order to train muscles effectively, the blinding was difficult in this trial. The blinding for nursing staffs was not possible neither because the intervention was carried out at daily use nursing spaces in the facilities. The

experiments and measurements for all groups were completed in the same period from July to November 2006.

2. Participants

The inclusion criteria were women over seventy years old who had SUI defined by the Diagnostic Questionnaire for Urination Difficulties of Elderly³⁰⁾³¹⁾, who had cognitive impairment evaluated as slightly to highly impaired levels by the Karasawa's Clinical Criteria for Grading Dementia³²⁾, who could be aware of bladder sensation, who could respond to the prompted voiding and who could perform the new pelvic floor exercise under guidance. The exclusion criteria were persons who had undergone cystectomy or hysterectomy, who had polyuria related to a metabolic/endocrinal disease and whose residual urine volume was zero or 150 mL and over. In general, the criterion for a normal residual urine volume is less than 50 mL, but since the criterion for possible refractory complications can be 100-150 mL, more than 150 mL was used as an exclusion criterion in this study. The Diagnostic Questionnaire for Urination Difficulties of Elderly is a tool to identify the urinary incontinence type, which consists of thirteen items, developed for physician, nurse and nursing care staff use. The Karasawa's Clinical Criteria for Grading Dementia was developed to evaluate the severity of cognitive impairment, which consists of two sound levels and four abnormal levels in activities of daily living and communication. Scores over 1 indicate cognitive impairment and the higher value means a severer condition. A total of sixteen females out of over one hundred older women were included in the study and allocated into either the intervention group or the control group by nursing units.

3. Outcome measures

The primary outcome was the amount of urinary leakage. The secondary outcomes included frequency of urinary leakage, urinary frequency and the post-void residual urine volume.

The amount of urinary leakage, leakage frequency and urinary frequency were based on the bladder diary for consecutive three days. The bladder diary was documented only in day-

time from 9 a.m. to 5 p.m., because observation during nighttime was too inconvenient for the participants and also for the care staff of the facilities. The amount of leakage was quantified in the four-degree scale as follows: 'none'=0, 'a little'=1, 'profuse'=2, and 'quite profuse'=3.

It has been reported that an increase in residual urine can be observed as an obstructive symptom due to degeneration of pelvic floor muscles in SUI cases³³⁾³⁴⁾. Traditionally, difficulties to hold and store urine in the bladder have been recognized as the major symptom of SUI, but in contrast, the difficulty of emptying the bladder in SUI cases has not been well noticed. The small attention might be due to the low clinical importance of emptying difficulty compared to involuntary leakage problems in SUI. However, both storing and voiding disorders could contribute to the morbidity of SUI, and increase in the residual urine volume should be one of the important concerns in the elderly SUI cases. Since the elevated residual urine volume is due to degeneration of the pelvic floor, the residual urine volume could become a parameter to examine the pelvic floor condition concerned with its tone and contraction ability. The technology of non-invasive examination methods has improved, and the validity of residual urine measurement with a portable ultrasound device has been practical in older adults. In this study, the residual urine volume was measured with a portable ultrasound device (Bladder Scan[®] BVI6100, Verathon Inc., USA, 3.7MHz, B mode, scan angle 120°), which reliability for residual urine volume measurement in nursing home residents was already proved³⁵⁾. The residual urine volume was measured three times immediately after urination during the bladder diary recording period, and the average volume was adopted for analyses. The measurement was conducted by a researcher and the intra-assay coefficient of variance of residual urine measurement was 15.0% in this study.

Additional information about age, nursing need level based on the Long-Term Care Insurance system in Japan, medical history, the Karasawa's Clinical Criteria for Grading Dementia, the Katz-

index of activities of daily living (ADL)³⁶⁾, parity, body mass index (BMI), medication and daily rehabilitation contents were documented for each participant.

4. Intervention

The pelvic floor muscle exercises newly designed for the study are shown in Table 1. The exercise aimed to contract the pelvic floor muscles using concomitant activities with adductor muscles and quadriceps femoris muscles. First, in order to design a new exercise for the older people in the long-term care facilities, we needed to consider the preconditions reflecting boundary status of the participants, such as low back pain, gonarthrosis or limited activities of daily living. According to the participant circumstances, we decided to perform the exercise at a seated position. The requirements for the exercise were as follows: 1. easy to contract the target muscles, 2. moderate loading without adverse effects, 3. corresponding to the type of target muscle fibers, and 4. simple contents to carry on. Bø reported that the pelvic floor muscles of young asymptomatic women were constructed synergistically when each hip adductor and gluteal muscle contraction was indicated³⁷⁾. The adductor muscles contribute to adduction/abduction and internal/external rotation of the femur³⁸⁾. On the other hand, the fibers of quadriceps femoris muscle originate from the tendon of the adductor magnus muscle³⁹⁾. Because of such anatomical linkage, quadriceps femoris can cause concurrent activation of adductors. In addition, the quadriceps femoris seemed to be easy to recognize and voluntarily contract or relax for older adults. Since the levator ani muscle consists of both type I and type II fibers⁷⁾, isometric exercise with intermittent relaxation, which mobilizes and hypertrophies both types of fibers⁴⁰⁾, should have been required. Such cross-sectional area is also likely to be mobilized by isotonic exercise and low intensity/high volume exercise might have been safe and effective⁴⁰⁻⁴²⁾. According to these considerations, three types of exercise including low intensity/high volume isometric and high intensity/low volume isotonic training were adopted after consultation

with physical therapists, occupational therapists, nurses and nursing staffs in the study facilities (Table 1). The repetition, frequency and duration of the exercises were determined, referred to previous trials on older adults with stress and urge incontinence²⁰⁾⁴³⁾.

The participants were asked to participate in one series of the exercise per day for eight consecutive weeks. Cognitive function and motivation to continue of the participants were considered, the exercise was performed on rhythm in a good mood and each movement was explained as simply as possible every time. A small soft ball was applied to induce concentration on the adductor muscles. A series of exercises took approximately fifteen minutes to complete and was conducted by the same researcher, supported by nurses and nursing staffs at the facilities. For the participants without severe cognitive difficulties, the exercises were performed in small groups. When there were any difficulties to perform the exercise due to cognitive decline, the participant was guided individually by the researcher. The intervention would be called off when any side-effects related to the exercise should have appeared among the participants. The participation in exercises was documented individually.

The flow of the participants is shown in Figure 1. The examinations on each outcome were

carried out before and after the intervention period. The bladder diary was documented by nursing staffs or nurses, but by the participant oneself when one's toileting was independent. Urination and the Katz-index of ADL were recorded by nursing staffs or nurses and finally confirmed by the researcher. Other data were collected by chart reviews and interviews with each participant.

5. Ethical considerations

A researcher explained about the study, the right to refuse or cease to participate and the protection of personal information to each older person. When the person seemed not to understand the study program very well, her proxy asked to receive the explanation together. The written informed consent was obtained from all participants and/or proxies. All processes of this study were carried out under the regulations of the Ministry of Health, Labour and Welfare; 'The Ethical Guide for the Epidemiologic Studies'.

6. Data analysis

All the statistical analyses were performed by SAS® (SAS Institute, Inc., Cary, NC). Each characteristic of the participants at the baseline was shown as median and examined whether there was any significant difference between the intervention group and the control group using Wilcoxon rank sum test. A general liner model

Table 1 New pelvic floor muscle exercise for older women

1. Warm-up exercise for hip joints.

Sits on the edge of a chair with armrests and stamps one's feet. (×20)

2. Isometric exercise of adductor muscles to contract the levator ani muscles synergistically.

Put a ball between one's thighs and press for 15 seconds.

(×3, the relaxing intervals will be the same long with each contraction time)

3. Mobilizing the fast-twitch fiber of levator ani.

Open/close one's legs from side by side, lifting one's soles, as widely as possible.

It's important to close one's knees together when legs closed.

(while singing a song, 32×2, taking breaks if needed)

Perform 1~3 once a day.

Each movement should be explained every time as to its purpose as well as how to contract the target muscle.

Take breaks between each movement for muscle relaxation.

Do not perform when there is pain at knees or hip joints.

was used to test whether each outcome measure differed between the groups after the 8 weeks intervention, shown in the least-squares mean by adjusting with the baseline values. Adjustment was also made for participant characteristics by each outcome measure with correlation, confirmed by Spearman rank-order correlation ($p < 0.20$). Possible reasons for outliers were examined, but there were no outliers to be excluded. All models used the Type III sum-of-squares method. Values of $p < 0.05$ were considered statistically significant.

Results

1. Participant characteristics

At the baseline, there were 8 people in each group. Three people were withdrawn from the study during the intervention period, and 6 participants remained in the intervention group and 7 remained in the control group. The cause of withdrawals was not related to

the intervention including the new pelvic floor muscle exercise introduced in this study. The exercise was carried out for 56 days totally, and the average participation days were 40.5 (range, 30.0-56.0) for the 6 people in the intervention group. Two participants of the control group were excluded from the analyses due to protocol violation, since each of them had performed a different exercise of adductor muscles under an individual rehabilitation program at the facility. Statistical analyses were conducted on 11 participants (Figure 1).

The main medical history was as follows (the number in parentheses denotes the participant numbers): skeletal and muscle disease (8), neurological disease (8), hypertension (5) and gastro-enterological disease (2). There were no cases of the inner pelvis diseases. The type of urinary incontinence and other demographic data are shown in Table 2. There were no significant differences among two groups in age, nursing

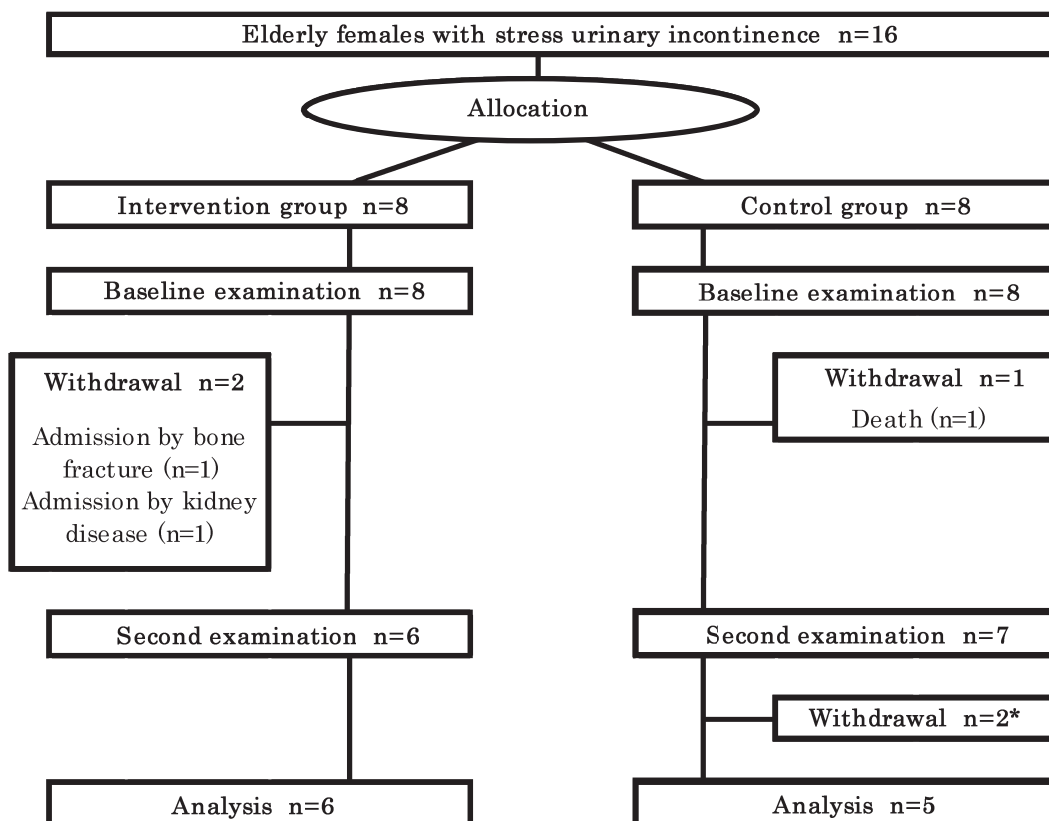


Figure 1 Flow diagram of participants

* Two participants were out of protocol due to individual rehabilitation program at the facility.

need level, parity and the Karasawa's Clinical Criteria for Grading Dementia. The Katz-index of ADL showed a significant difference among two groups, and people in the control group had relatively higher levels in ADL ($p=0.026$).

2. Outcomes

At the baseline, there were no significant differences between two groups in urinary frequency, leakage frequency, amount of leakage and the post-void residual urine volume (Table 2).

During eight weeks of the intervention period, the average residual urine volume changed from 29.7 (range, 20.0-80.0) mL to 4.5 (range, 0-57.0) mL

in the intervention group and from 52.3 (range, 29.7-140.0) mL to 64.3 (range, 37.0-147.3) mL in the control group. There was a significantly larger decrease in the residual urine volume in the intervention group than the control group ($p=0.009$) (Table 3). In the intervention group, 5 out of 6 participants had a decline in the residual urine after the intervention period. One participant in the intervention group had an increase in the residual urine volume, who suspended exercises because of having a cold. In the control group, the residual urine volume increased in all five people. Each post-void residual volume change is shown in Figure 2.

Table 2 Participant basic characteristics and type of incontinence at the baseline

	Intervention group (n=6)	Control group (n=5)	<i>p</i> -value
Age(year)	84.5 (73 – 90)	86.0 (78 – 93)	0.583
Nursing need level *	3.0 (1 – 4)	3.0 (3 – 4)	1.000
Number of delivery	2.5 (0 – 3)	2.0 (0 – 3)	0.570
Body Mass Index (kg/m ²)	16.7 (15.7 – 26.7)	22.9 (16.4 – 24.5)	0.235
Karasawa's Clinical Criteria †	2.0 (1 – 3)	3.0 (1 – 3)	0.768
Katz-index of ADL	3.0 (1 – 5)	6.0 (4 – 8)	0.026
Urinary Status ‡			
Residual urine volume, mL §	29.7 (20.0 – 80.0)	52.3 (29.7 – 140.0)	0.235
Urinary frequency	10 (9 – 17)	9 (7 – 20)	0.774
Leakage frequency	4 (0 – 9)	4 (4 – 11)	0.502
Amount of urinary leakage ¶	1 (0 – 2)	1 (0 – 2)	1.000
Type of incontinence, n #			
Stress incontinence	3	1	–
Urge incontinence	0	0	–
Mixed incontinence	3	4	–
Functional incontinence **	5	5	–

Median (range)

Wilcoxon rank sum test

* Nursing level is based on the Long-Term Care Insurance system in Japan

† Karasawa's Clinical Criteria for Grading Dementia; evaluates dementia by two sound levels and four abnormal levels from behavioral conduct. A score >1 means dementia.

‡ Urinary frequency, leakage frequency, and the amount of urinary leakage were surveyed during daytime from 9 a.m. to 5 p.m.. Each result shows the average in three days.

§ Residual urine volume was measured three times immediately after urination, and the average was adopted.

¶ Extent of wetness was quantified visually: none=0, a little=1, profuse=2, quite profuse=3, and was added up in the daytime for three days.

The Diagnostic Questionnaire for Urination Difficulties of Elderly; defines the type of incontinence by 13 score-adjusted questions.

** All functional incontinence cases were duplicated with other types of incontinence.

Table 3 Urinary status in eight-week intervention

	Adjusted Least-Squares Mean (95% Confidence Interval)		<i>p</i> -value
	Intervention group (n=6)	Control group (n=5)	
Residual urine volume (mL) *	24.2 (9.4 – 39.0)	65.9 (49.2 – 82.7)	0.009
Urinary frequency †	13.9 (3.2 – 24.6)	4.7 (-7.8 – 17.2)	0.206
Leakage frequency	3.5 (0.8 – 6.1)	1.5 (-1.5 – 4.5)	0.327
Amount of urinary leakage ‡	6.5 (2.6 – 10.5)	0.6 (-3.3 – 5.0)	0.076

general linear model

* Residual urine volume was measured three times immediately after urination, and the average was adopted.

† Frequency of urination, urination with awareness, wet episodes, and extent of wetness were surveyed in the daytime from 9 am to 5 pm. Each result shows the sum of three days' frequency or extent.

‡ Extent of wetness was quantified visually: none=0, a little=1, profuse=2, quite profuse=3, and was added up in the daytime for three days.

The analyses of outcomes are controlled by baseline values. Adjustment was made for participants' characteristics (1. Age, 2. Nursing need level, 3. Katz index of ADL, 4. Number of delivery, 5. Body mass index, 6. Karasawa's clinical criteria for grading dementia) which correlate each outcome measure confirmed by Spearman rank-order correlation ($P < 0.2$); 3, 5, 6 for residual urine volume; 4 for frequency of urination; 1, 2, 3 for wet episode, 1, 2, 3 for extent of wetness, respectively.

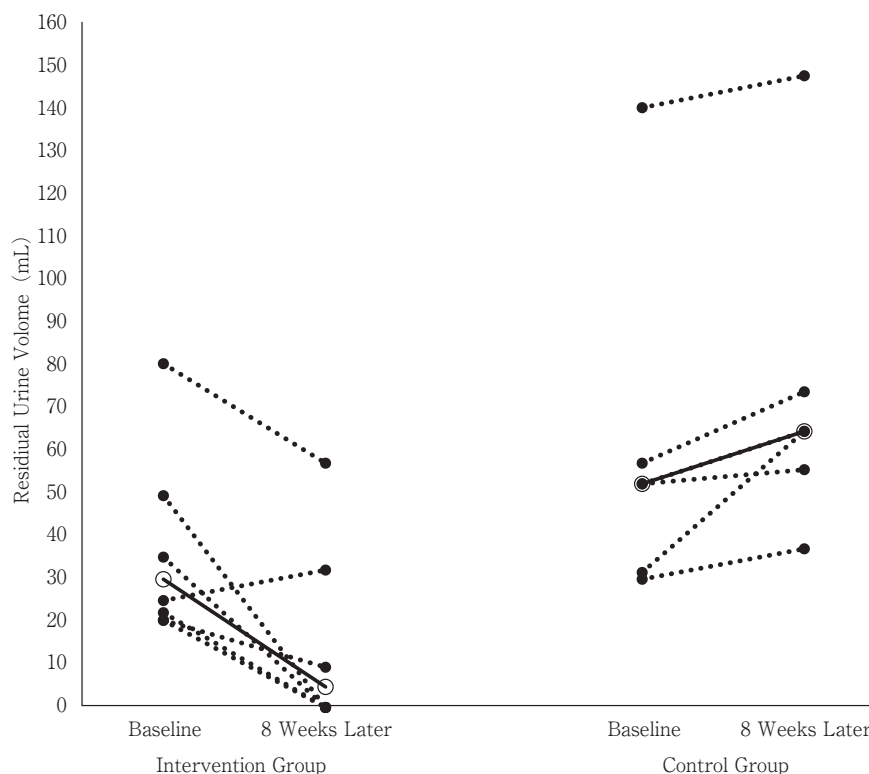


Figure 2 Change in the residual urine volume

Each participant's change in post-void residual urine volume is represented. Five out of six people had a decline in residual urine after 8 weeks in the intervention group, otherwise, all five people had an increase in the control group. The broken lines with closed circles indicate individual values. The full lines with open circles show the group median for each time point.

There were no significant differences among two groups in changes in the amount of urinary leakage, leakage frequency and urinary frequency. The participant urinary status is shown in Table 3.

Discussion

This study demonstrated the effectiveness of the new pelvic floor muscle exercise for older women with cognitive impairment at the long-term care settings. The exercises could reduce the residual urine volume in eight weeks, that is, it might be effective for emptying difficulty of the participants. This result suggests the possibility of attenuating urinary problems in older women by the new exercise, even though they have a cognitive decline.

In the study, the originally designed pelvic floor muscle exercise significantly decreased the residual urine volume in the intervention group compared to the control group. The residual urine volume of five out of six participants in the intervention group was decreased at the completion of eight-week exercise. That is, the new pelvic floor exercises may have effectiveness on emptying difficulty in SUI cases at the long-term care facilities. The participants performed isometric and isotonic trainings on the adductor muscles, which was expected to induce concomitant contraction of pelvic floor muscles. The significant decrease of residual urine in the intervention group shows the possibility that a synergistic training method for the pelvic floor muscles using adductor muscle training is effective to improve voiding function in SUI cases in older women. Further research is needed to prove synergistic contractions between pelvic floor muscles and adductor muscles.

The apparent reduction in the residual urine volume after pelvic floor muscle exercises indicates that there was pelvic floor muscle degeneration related to the increase in the residual urine volume among the participants, that is, there could be an obstructive dysfunction in SUI⁴⁴). The emptying disorder presented by the residual urine in the SUI cases of this study could be based on weakness of the pelvic floor

muscles but not on urethral occlusion. The residual urine volume observed in this study was smaller than the typical obstructive cases, for example, the cases with overflow incontinence. Further research is needed to clarify the significance of voiding function in SUI and explain the pathophysiological meaning of the residual urine in this condition. Moreover, the examination on residual urine volume in SUI requires precise tool in measuring the very low levels of residual. The present study showed the possibility of examining the residual urine volume in SUI cases by a portable ultrasound device non-invasively. However, there remains concerns about the accuracy of the measurement tool and the inter-rater reliability when several examiners are involved in the examination. The difference between the groups observed in this study indicates a clinically meaningful effect, given that the coefficient of variation was about 15%.

The new pelvic floor muscle exercise in this study have not showed any significant influence on urinary status including leakage, the major disorder of SUI. One of the reasons could be the high prevalence of functional incontinence among the participants and it might have compromised the effectiveness of the exercise. The accessibility to toilet in consideration of cognitive function and physical mobility should have been ensured as the study environment at the facilities. The other reason could be the partial effectiveness by the exercise. Petros suggests that the emptying difficulty which causes residual urine is due to weakness of middle or posterior part of the pelvic floor⁴⁵). Otherwise, Delancey & Ashiton-Miller mentioned that weakness of the urethral support due to the alteration of pelvic floor around vagina could preclude the reactive constriction of a urethra, resulting in urinary leakage in SUI⁴⁶). The exercises in this study might strain a partial zone of the muscles, or the duration of exercises might not be enough to strain the particular part of pelvic floor which is responsible for urinary leakage. Further research is needed to prove which part of the pelvic floor muscles is induced by the exercises, and which type of exercises can work for at-

tenuation of urinary leakage in SUI cases.

There were no withdrawals due to incompletion with the new pelvic floor muscle exercise in this study. Since each participant had cognitive impairment, the exercise needed to be correspondingly easy and simple to understand, to contract proper muscles and to promote participation for a long period. The exercise method which mobilize quadriceps femoris or the supportive tool such as a small ball between thighs seemed to help the participants recognizing the particular muscle to concentrate appropriately. Moreover, joyful atmosphere during exercises and the face to face intervention in severe cognitive decline cases might enhance the motivation to the exercise. The procedure of the pelvic floor muscle exercise in this study which particularly focused on vulnerable older women was notably acceptable, promoting continuous participation with no dropouts. In the end, the exercise showed potential effectiveness for urinary problems related to the residual urine among the frail population in long-term care facilities.

Limitation

There are several limitations in this study. A non-blinded process might have influenced the participant positive perspective and their toileting behaviors. A non-randomized allocation would disturb generalization. Three study units belonged to different facilities and some minor differences in continence care for each setting might have been the potential bias associated to the results. The limited number of participants, short bladder diary and intervention period would preclude exact evaluation of the exercise effects on the urinary problems in SUI. A large scale randomized and blinded study is needed in the future.

Conclusion

In this pilot study, the originally designed pelvic floor muscle exercise was carried out for eight weeks to the older women with cognitive impairment at the long-term care facilities. The new exercise was acceptable for the participants to conduct continuously and seemed to reduce the

residual urine volume in the SUI cases. The result indicates the residual urine is a concomitant condition of SUI in older women and the physical therapy may improve their urinary problems related to the residual.

Contributions to the Manuscript

Study design: SH; Data collection: SH; Data analysis: SH, GN, HS; Manuscript preparation: SH, GN, HS.

Ethical Process

The study was conducted by a graduate school student at three long-term care facilities under the same Japanese medical group in 2006. The study was not subjected by the ethical committee at the graduate school where the primary author was enrolled at that time, in addition, the medical group did not have an ethical committee for clinical studies in long-term care facilities. In consideration of such circumstances, we decided to perform the study very carefully under the regulations of the Ministry of Health, Labour and Welfare; 'The Ethical Guide for the Epidemiologic Studies' and consultations for chief nurses, a nursing director, a nurse educating director and a well-informed researcher about human rights of the older adults. We obtained written informed consents from every participant and their family members if necessary, protecting their right to claim on any explanation about the study and be free to withdraw from their participation throughout the study.

Acknowledgment

We are deeply grateful to every one of the participants and the facility members who participated and collaborated in the study. This paper would not have been possible without Professor Kinuko Takasaki, who gave immense guidance, support and encouragement to accomplish the clinical research. Sysmex Corporation was very helpful for preparation for the ultrasound device.

Conflict of Interests

The results of this study were not involved in

any supporting companies and affected from any conflict of interests. Each author has no conflict of interests such as affiliation with any supporting companies, funds, honoraria, royalties or patents about the study.

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認知機能が低下した女性高齢者の尿失禁に対する新しい骨盤底筋運動の効果： 予備的研究

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キーワード

認知機能障害, 高齢者, 骨盤底筋運動, 残尿量, 腹圧性尿失禁

要 旨

背景：腹圧性尿失禁（SUI）は、女性高齢者の日常生活に多大な影響を及ぼす。長期療養施設では運動障害や認知機能障害のために有効な運動療法がなく、SUIの管理が困難である。この予備的研究の目的は、認知機能が低下したSUIを有する女性高齢者に対し、新しい骨盤底筋運動の効果を検証することである。

方法：SUIを有する長期療養施設の16人の70歳以上の女性高齢者に対し、非ランダム化比較試験を行った。介入群には1日1回骨盤底筋運動を実施し、対照群には排尿自覚刺激行動療法と定時誘導を含む通常ケアのみを行ない、3日間の日中の排尿日誌と残尿量を記録した。

結果：介入群6人と対照群5人が調査を完了し、8週間後、介入群で残尿が有意に減少した（ $p=0.009$ ）。尿もれの頻度や量には有意な変化がなかった。

結論：新しい骨盤底筋運動は、認知機能が低下した女性高齢者の残尿を減らす効果があった。この結果から女性高齢者の腹圧性尿失禁には残尿が伴い、運動療法によって改善の可能性があることが示唆された。